

**Amendments to the Drawings:**

The attached sheet of drawings includes changes to Fig. 4, 5 and 6. These drawing sheets, which includes Figs. 4, 5 and 6, completely replace the original sheets including Figs 4, 5 and 6. In these Figs., omitted elements 40 and 40' have been added. In addition, some of the wording has changed within the drawings.

***Attachment:***                    ***Replacement Sheet***  
***Annotated Sheet Showing Changes***

## REMARKS AND ARGUMENTS

Claims 2-11 and 14-19 have been canceled. Claims 1, 12, 13, and 20-72 are now pending in the application and presented for examination.

Claims 1, 12, and 13 are currently amended. Claims 20-72 are new.

The Examiners are thanked for having graciously held a telephone interview with the undersigned on October 4, 2007.

As mentioned in the interview, in a *bona fide* attempt to advance the application to allowance and better understand the prior art cited by the Examiner that relates to devices for veterinary use, Applicants sought the assistance of a registered patent attorney who is also a licensed veterinarian. The amendments and new claims presented here were not presented earlier because they reflect the recently-received assistance of this individual.

Reconsideration of the outstanding objections and rejections is respectfully requested for the reasons that follow.

### Drawings

The drawings were objected to under 37 CFR § 1.83(a) for failing to show every feature of the invention specified in the claims. Specifically, the Examiner noted that an “antenna” as claimed in claims 1, 14, and 16-19 was not shown in the drawings.

Three replacement drawing sheets in compliance with 37 CFR § 1.121(d) are submitted herewith. Replacement Figures 4, 5, and 6 each show an antenna (40) as an element of the probe unit and an antenna (40') as an element of the control unit.

No new matter has been entered as a result of these amendments. Support for an antenna as an element of the probe unit appears in the original specification at least on page 6 at lines 13-15 (“The stimulator unit 21 is furthermore provided with ... an antenna”), and support for an antenna as an element of both the probe unit and the control unit appears in the original specification at least on page 8 at lines 14-17 (“In particular, the stimulator unit 21 and control unit 22 respectively include ... a transceiver 36, 36' which includes an antenna.”).

Applicants have amended the specification concurrently to include the reference characters of the antenna elements shown in the replacement drawings.

Additionally, in each of the replacement drawing sheets, "I.C." has been deleted from the label of the representation of the microprocessor (35) of the probe unit (21) because this part of the label was not sufficiently explained in the written description.

Applicants respectfully request that the original three sheets of drawings for Figures 4, 5, and 6 be replaced with the attached three replacement drawing sheets for Figures 4, 5, and 6, and that the objections to the drawings be withdrawn.

### **Claim Rejections – 35 USC § 112**

#### ***A. Rejections Under 35 USC § 112, First Paragraph***

Claims 16-19 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated that the original disclosure of the application failed to provide support in full, clear, concise, and exact terms that the combination probe, transceiver, and power source is (a) non-expandable and non-compressible in cross-section, or (b) insertable into a vagina without the use of a tool.

Applicants have now canceled claims 16-19. The limitations identified by the Examiner as insufficiently supported are not recited in any currently pending claims. Applicants respectfully submit, therefore, that this rejection is moot and request its withdrawal.

#### ***B. Rejections Under 35 USC § 112, Second Paragraph***

Claims 1-13, 16, 17, and 19 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In particular, the Examiner stated that the limitation "non-implanted" recited in claims 1 and 16 rendered the claims indefinite.

Applicants continue to respectfully traverse this rejection and disagree with the Examiner that the limitation "non-implanted" is indefinite, for reasons detailed in previous communications. However, in an effort to advance the prosecution of the application, Applicants have canceled claims 2-11, 16, 17, and 19, and amended claim 1 to delete the limitation "non-implanted."

This limitation is not now recited in any currently pending claim. Applicants respectfully submit, therefore, that this rejection is moot and request its withdrawal, and they respectfully request reconsideration of amended claims 1, 12, and 13.

### Claim Rejections – 35 USC § 102

#### A. *Anticipation By Mehrotra et al.*

Claims 1-7, 11-13, 16, 17, and 19 were rejected under 35 U.S.C. § 102(e) as being anticipated by Mehrotra et al. (U.S. Pat. No. 6,860,859).

Applicants respectfully disagree with the Examiner, but to advance the prosecution of the application, have now canceled claims 2-7, 11, 16, 17, and 19. Claim 1, and thus its dependent claims 12 and 13, has been amended to require, among other things, that the system claimed comprises a combination probe provided with means for stimulating perineal musculature and/or nerves.

Applicants respectfully submit that Mehrotra does not teach or suggest a vaginal probe provided with means for stimulating perineal musculature and/or nerves. Accordingly, Mehrotra does not describe every element of the Applicants' invention and thus Applicants respectfully request that the rejection be withdrawn and amended claims 1, 12, and 13 be reconsidered.

Claim 1, and thus its dependent claims 12 and 13, also has been amended to require that the system claimed comprises a combination probe adapted to be entirely contained within a human's own vagina. Applicants respectfully disagree with the Examiner that Mehrotra teaches an intravaginally containable combination probe which integrates a transceiver, an antenna, and a power source. Mehrotra describes only devices that are partially intravaginally containable, with any signal transmitting means of these devices located on the portions of the devices that are outside the mammal's body and not contained within the vagina. Mehrotra repeatedly teaches that the communication means of the described device should not be contained within the vagina, as can be seen in Figure 2 and the verbal examples here:

- “said transmitting means being suitable to be held in continuous proximity to the mammal's body during the time of said measuring, converting and transmitting, of the signal” (column 3, lines 24-27);

- “when the housing is within the mammal’s vagina, said sending means is substantially external and proximal with respect to the mammal’s body” (column 3, lines 34-37);
- “The extension being of such dimension and position on the apparatus so as to provide for a portion which is exterior to the mammal when the apparatus is inserted into the mammals [sic] vagina.” (column 4, lines 3-6);
- “The sensed condition, data or information is transmitted as signals (electronic or otherwise) representing each of said conditions from a location proximal and exterior to the mammal’s body.” (column 5, lines 9-12).

Although Mehrotra does not disclose why the communication means should not be contained within the vagina, Applicants believe the reason to be that Mehrotra’s communication means could not function adequately when so contained because of the significant attenuation and distortion of wireless signal transmission and reception imposed by a mammalian body. This signal attenuation and distortion was a problem in the prior art that Applicants’ invention has overcome. Mehrotra does not teach or suggest how to overcome this problem and would have had no reasonable expectation of success in overcoming it, and thus Mehrotra does not teach or suggest a combination probe such as the Applicants claim that has a transceiver capable of functioning wirelessly in real time while entirely contained within a mammal’s vagina. Mehrotra’s apparatus is only partially intravaginally containable, and Applicants believe that the apparatus Mehrotra describes could not function if the signal transmitting means of the apparatus was contained within a vagina.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims under 35 U.S.C. § 102(e) as being anticipated by Mehrotra et al. because Mehrotra fails to describe each and every element of Applicants’ claims. Applicants respectfully request that amended claims 1, 12, and 13 be reconsidered.

***B. Anticipation By Guice et al.***

Claims 1-7, 11-13, and 16 were rejected under 35 U.S.C. § 102(e) as being anticipated by Guice et al. (U.S. Pat. Appl. Pub. No. US 2002/0010390).

Although Applicants respectfully disagree with the Examiner, in an effort to advance the prosecution of the application, claims 2-7, 11, and 16 have been canceled, and claim 1, and thus its dependent claims 12 and 13, has been amended.

Claim 1, and thus its dependent claims 12 and 13, has been amended to require, among other things, that the system claimed comprises a combination probe provided with means for stimulating perineal musculature and/or nerves. Applicants respectfully submit that Guice does not teach or suggest a vaginal probe provided with means for stimulating perineal musculature and/or nerves or for affecting any vaginal condition. Accordingly, Guice does not describe each and every element of the Applicants' invention and Applicants respectfully request withdrawal of the rejection and reconsideration of amended claims 1, 12, and 13.

Additionally, claim 1, and thus its dependent claims 12 and 13, has been amended to emphasize, among other things, that the system claimed comprises a probe provided with two-way communication means and a controller provided with means for sending signals to the probe and for receiving signals therefrom wirelessly and in real time, wherein a wireless signal feedback loop is provided between the controller and the probe in real time during operation of the system. Applicants respectfully disagree with the Examiner that Guice discloses a wireless signal feedback loop between the controller and the probe and submit that any back-and-forth wireless transmissions that may occur between components of Guice's system do not occur in real time. The paragraph identified by the Examiner as supporting this disclosure, [0209], clearly indicates that the disclosed control unit can only either transmit or receive wireless signals at any particular point in time, as with "voice walkie-talkies and other personal radio devices," and cannot both transmit and receive signals at the same time. The type of communication Guice discloses is not wireless real-time two-way communication. Nowhere does Guice teach or suggest wireless real-time two-way communications between a controller and a probe such that a wireless signal feedback loop is provided in real time during operation of the system.

Accordingly, Guice does not describe each and every element of the Applicants' invention and Applicants respectfully request withdrawal of the rejection and reconsideration of amended claims 1, 12, and 13.

### **Claim Rejections – 35 USC § 103**

***A. Unpatentability Over Eini et al. In View Of Mehrotra et al.***

Claims 8-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Eini et al. (U.S. Pat. No. 6,432,037) in view of Mehrotra et al. (U.S. Pat. No. 6,860,859).

Claims 8-10 have been canceled. Applicants respectfully request withdrawal of this rejection, therefore, because it is now moot.

***B. Unpatentability Over Blythe In View Of Mehrotra et al.***

Claims 1-7 and 11-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Blythe (U.S. Pat. No. 6,080,118) in view of Mehrotra et al. (U.S. Pat. No. 6,860,859).

In an effort to advance the prosecution of the application, claims 2-7, 11, and 14-19 have been canceled. Claims 1, 12, and 13 have been amended to require, among other things, that the system claimed comprises a combination probe adapted to be entirely contained within a human's own vagina.

Applicants respectfully disagree with the Examiner that Blythe teaches an intravaginally containable combination probe and power source. Blythe describes a vaginal probe having two ends: an insertable end portion and an external end portion. Blythe teaches that a battery may be included in the external end portion only. Blythe discloses that "[i]n use, the insertable end portion 14 of the probe 10 is inserted into the subject's vagina 20 ... with the external end portion 16 maintained external to the patient." Column 7, lines 38-42. Blythe does not teach or suggest a probe including a power source that is containable within a vagina. The portion of Blythe's probe that is intended for insertion into a vagina does not include a power source; the portion of Blythe's probe that may include a power source is not intravaginally containable.

Moreover, as the Examiner admitted, Blythe fails to disclose a transceiver in either the probe unit or the controller unit.

Mehrotra et al. does not teach or suggest the elements of Applicants' claims that Blythe fails to describe. As discussed above, Mehrotra describes only devices having

signal transmitting means that are, by functional necessity, located outside a mammal's body during the time of measuring and transmitting to a receiving station. *See, e.g.*, Fig. 2. Mehrotra does not teach or suggest how to overcome the significant attenuation and distortion of wireless signal transmission and reception that is imposed by a mammalian body and would have had no reasonable expectation of success in overcoming it, and thus does not teach or suggest a combination probe capable of functioning while entirely contained within a mammal's vagina as Applicants claim. Mehrotra's apparatus, like Blythe's, is only partially intravaginally containable, and thus Applicants submit that not only do neither Blythe nor Mehrotra disclose an intravaginally containable probe with two-way communication means, but neither of the devices described by Blythe and Mehrotra could function adequately if their signal transmitting means were contained within a vagina.

Accordingly, Applicants respectfully request withdrawal of the rejection and reconsideration of amended claims 1, 12, and 13.

### **Additional Remarks Supporting Amendments and New Claims**

#### ***A. Support for Limitations Appearing in Claims for the First Time***

In an effort to assist the Examiner in examining the amended and numerous new claims submitted herewith, Applicants agreed in the telephone interview of October 4, 2007, to point out at least some places where support can be found for certain limitations appearing in the claims of this application for the first time.

Claim 1 has been amended to require that the combination probe is substantially cylindrical. Support for this limitation can be found at least in the drawing of an embodiment of the combination probe (21) in Figure 1.

Claim 1 has been amended also to require that the combination probe has a substantially smooth and substantially sealed outer surface. In addition to Figure 1 showing such an outer surface on the combination probe depicted therein, support for these limitations can be found in the written description at least on page 3 at lines 20-21 ("The probe of the inventive system contains no wires or similar external means or



surface controls”) and on page 11 at lines 6-7 (“the combination probe and transceiver unit 21 is a sealed unit”).

Applicants have amended claim 1 to emphasize that the combination probe claimed is adapted to be entirely contained within a human’s own vagina. Support for this amendment can be found in the original specification at least at page 3, lines 2-3 (“portable, non-implanted, intravaginally containable (i.e. in situ yet removable)”) and at the last line of page 6 and first line of page 7 (“The stimulator unit 21 is then inserted into the vagina.”). That the probe can be entirely contained within a vagina is also evident by the disclosure in the original specification, at page 6, lines 3-6, of an embodiment having an end “rounded to facilitate vaginal insertion” and an opposite end that “can be provided with, for example, an eyelet 25 to which a cord or similar device can be attached to facilitate removal of the reusable unit.” Applicants respectfully submit that a probe such as those described by Mehrotra et al., Blythe, and Eini et al. would have no use for a means to facilitate removal from a vagina because a portion of each of those probes of the prior art always remains external to the vagina and thus accessible to be readily grasped and removed.

Additionally, that the probe claimed in amended claim 1 is adapted to be contained within a human’s own vagina is supported at least by the first paragraph on page 4 of the original specification: “When the probe unit of the inventive system is used as a stimulation unit, women are provided a safe, easy and convenient way to strengthen and tone their pelvic muscles without professional intervention or special training.” The last paragraph on page 3 lends further support: “The probe of the inventive system contains no wires or similar external means or surface controls, and is therefore comfortable to use.”

Amended claim 1 also requires that the combination probe is adapted to ergonomically insert into and be removed from a human’s own vagina. The support mentioned above for the limitation that the probe is adapted to be entirely contained within a vagina supports these limitations. Additionally, support for these limitations can be found at least on page 11 at line 3, referring to the “ergonomic character of the probe,” and on page 8 at lines 1-2 (“The stimulator unit 21 can then be removed.”).

New claim 48 requires that the probe unit be adapted to be comfortably, temporarily, and repeatedly inserted into, contained entirely within, and removed from a user's vagina. The portions of the specification identified above as supporting the amendments to claim 1 also support these limitations of claim 48. Additional support for these limitations is provided by the following examples from the specification:

- page 4 at lines 16-18 (“physiological information can be wirelessly tracked and monitored, allowing observation and supervision of metabolic and fertility activities”);
- page 6 at line 19 (“To begin a session ...”);
- page 8 at lines 3-4 (“a session ... could run for approximately 15 minutes”);
- page 8 at lines 8-9 (“The stimulator unit 21 can be programmed so that it will automatically ramp up to the setting of a previous use”).

New claim 32 requires that the probe unit be so dimensioned as to permit comfortable and repeated insertion into, removal from, and containment entirely within a mammal's vagina. The portions of the specification identified above as supporting amended claim 1 and new claim 48 support these limitations of new claim 32. Additional support for claim 32 can be found at least on page 2 at line 8, where the system and method is described as intended for use “in the human or other mammalian vagina.”

Applicants respectfully request that the Examiner contact the undersigned by telephone with any question as to support for any element in any pending claim.

***B. Additional Remarks on the Patentability of the Invention***

Each of the claims now pending in the application comprises an entirely intravaginally containable probe unit comprising a two-way communication means with an antenna, capable of transmitting to and receiving signals from a control unit, wirelessly and in real time. Applicants submit that none of the prior art cited by the Examiner discloses a system including an entirely intravaginally containable probe unit comprising a two-way communication means with an antenna and capable of simultaneously transmitting to and receiving signals from a separate control unit, wirelessly and in real time. Where the prior art does disclose an intravaginally containable communication means, that communication means (a) is not wireless, (b)

cannot both transmit and receive signals, and/or (c) cannot both transmit to and receive controlling signals from a control unit simultaneously in real time.

Applicants note that Guice refers to the problems in the prior art associated with wireless signal transmission to and/or from a device buried deep within a mammalian body, as within a vagina, which Applicants mentioned above and have overcome with their invention.

- “For those telesensor implants 50, 51 and application environments where the combination and tradeoffs of implant RF transmitter power, antenna length, RF signal attenuation and propagation distortion by passage through tissue, receiver antenna and receiver quality, and other factors result in an RF to signal too weak or too distorted to be detected at ranges convenient for economic installation of receivers in the vicinity of the cattle pens, an ear tag, surface mountable patch, collar, or other device attached to the animal and containing or supporting either a simple RF boost and relay capability 58, (e.g., a transponder), or a signal detection, processing, and transmission capability 58 may be employed to obtain the additional range and other functions as described hereinafter.” [0087]
- “a percutaneous implant which enables use of an external, exposed antenna may offer significant offsetting advantages in terms of increased transmit and reception range and other benefits.” [0155]
- “One key advantage of a percutaneous implant is that an antenna may be exposed on the outside of an animal, thereby enabling use of a longer antenna than it may [sic] desirable to implant inside an animal, and also avoiding the attenuation and distortion of RF signals by the tissue of the animal which is a problem at some frequencies.” [0181]

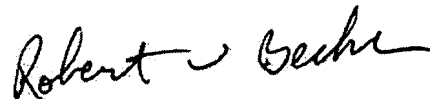
The limitations of the claims now pending in the application render the claimed subject matter novel and non-obvious over the cited prior art.

No new matter has been entered in conjunction with the amendments to claims 1, 12, and 13 or new claims 20-72. Support for each of the elements of each of these pending claims can be found in the original specification including the drawings and the written description. The courtesy of a telephone interview is respectfully requested should the Examiner have any question or concern relating to the patentability of Applicants’ invention.

Applicants believe that the application is now in condition for allowance and respectfully request reconsideration of the allowability of Applicants’ pending claims. In

view of the claim amendments and the remarks, further and favorable consideration of the presently pending claims and the early issuance of a Notice of Allowance with regard to all pending claims are respectfully requested.

Respectfully submitted,

A handwritten signature in black ink that reads "Robert W. Becker". The signature is written in a cursive style with a large, sweeping initial "R".

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ANNOTATED SHEET

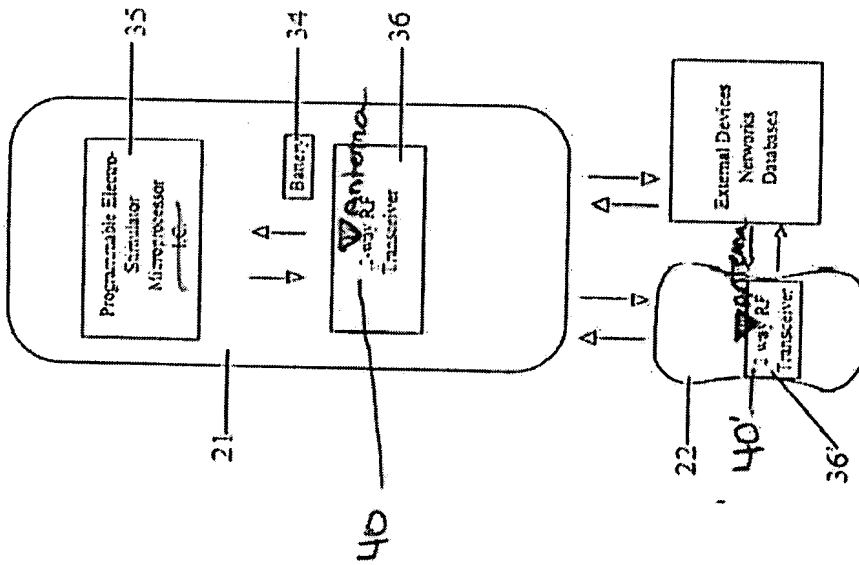


FIG. 4

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Joel S. Hochman, et al

ANNOTATED SHEET

FIG 5

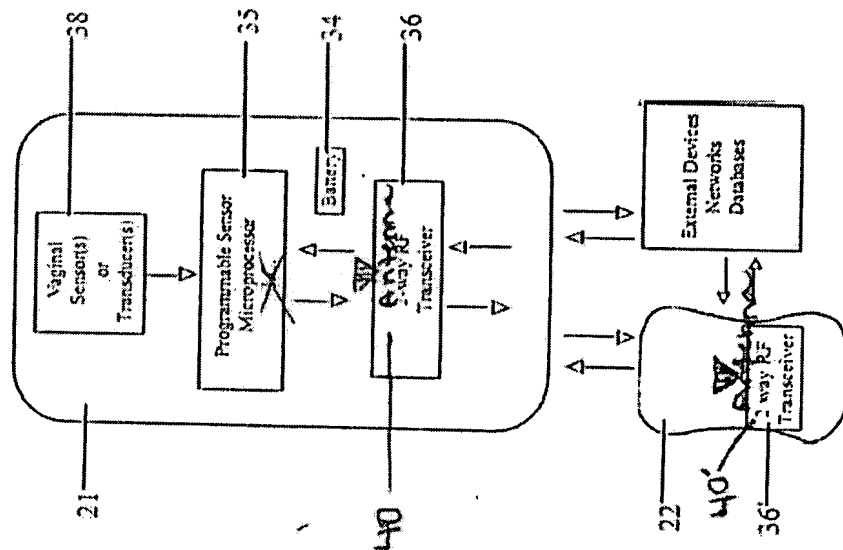


FIG 6

